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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,784	10/12/2001	Maximilian Polyak	053137-5001	2223

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,784

Applicant(s)

POLYAK ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 13-18 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-12, 19 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-28 are pending. Claims 1-5, 9-12, 19 and 28 are considered on the merits. Claims 6-8, 13-18, 20-27 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

Claims 1-5, 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "complex sugar" has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the inclusion of the genus of "complex sugar". There is only one exemplified "complex sugar" and that is raffinose. This is not sufficient support for the new genus "complex sugar". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of "complex sugar" is considered to be the insertion of new matter for the above reasons.

"Complex sugar" does not appear in the originally filed claims. "Complex sugar" appears only on page 5 [0018] of the disclosure where it is stated that "other components that may be utilized in the solution include ... and raffinose, which is a COMPLEX SUGAR that reduces cell swelling and provides energy stores for metabolically stressed cells." This is not the description of a genus of "complex sugars" and their inclusion into the claimed composition, but rather is merely an explanation of what the species, raffinose, is.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection of JP 06-305901 over claims 1-5, 12. However, removal of new matter may result in the reinstatement of the art rejection.

Claims 1-5, 12 are no longer rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 06-305901 [IDS] due to the insertion of new matter.

The claims are directed to a composition comprising:

- a) a cellular energy production stimulator (insulin),
- b) an anti-inflammatory agent (dexamethasone),
- c) an oxygen free-radical scavenger (SOD).

The references are relied upon as explained below.

JP 06-305901 discloses a composition comprising insulin, dexamethasone and PEGylated SOD.

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Claim Rejections - 35 USC § 102

Claims 1-4, 9-12, 19 and 28 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Caldwell-Kenkel *et al.* [U] in light of US 4,879,283 [IDS].

The claims are directed to a composition comprising:

- a) insulin 4-100U/L,
- b) dexamethasone 4-24 mg/L
- c) SOD 1000-100,000U/L,
- d) potassium lactobionate 50-150mM,
- e) KH_2PO_4 10-40mM,
- f) magnesium sulfate 2-8mM,
- g) raffinose 10-50mM,
- h) adenosine 1-20mM,
- I) allopurinol 1-10mM,
- j) pentastarch 40-60g/L.

Caldwell-Kenkel *et al.* disclose UW solution supplemented with c) SOD 25 U/ml (Table 6). UW solution is old in the art and is disclosed in US 4,879,283 as comprising:

- a) insulin 100 U/L,
- b) dexamethasone 8 mg/L
- d) potassium lactobionate 100mM,
- e) KH_2PO_4 25mM,
- f) magnesium sulfate 5mM,
- g) raffinose 30mM,
- h) adenosine 5mM,
- I) allopurinol 1mM,
- j) pentastarch 50g/L.

Use of the terms "about" in the claimed solution, without definition of the range of "about" permits interpretations that place the concentrations claimed to be "about" the disclosed concentrations.

Response to Arguments

Applicant's arguments filed 12/16/03 have been fully considered but they are not persuasive.

Applicants argue that Caldwell-Kenkel *et al.* teach away from the disclosed composition. However, one cannot "teach away" from an anticipatory reference. Either the composition is disclosed in the reference or it is not.

Claim Rejections - 35 USC § 103

Claims 1-4, 9-12, 19 and 28 remain/are rejected under 35 U.S.C. 103 as being obvious over Caldwell-Kenkel *et al.* [U] in combination with US 4,798,824 [IDS] or SU 1074471 [N].

The claims are further directed to the use of about 40 U/L insulin.

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Caldwell-Kenkel *et al.* has been discussed above.

SU 1074471 discloses the inclusion of 35-45U/l insulin in a solution for kidney preservation.

US 4,798,824 discloses the use of 40U/ml insulin in a solution for kidney preservation (Table 1).

The use of insulin in a range of 35-100U/L in the composition of Caldwell-Kenkel *et al.*, would have been obvious because insulin has been used in the prior art in concentrations of 35-100U/L for perfusion of organs such as kidney.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

All components of the claimed composition near the concentrations of the claims have been used in the prior art for the same purpose as the instant purpose. No claim is allowed.

Response to Arguments

Applicants argue that Caldwell-Kenkel *et al.* teach away from the inclusion of SOD in the cold storage solution. Please note that although Caldwell-Kenkel *et al.* state that the inclusion of SOD does not reduce endothelial cell killing after reperfusion, it is not considered that this is a statement of "teaching away" since the inclusion of SOD does not damage the cells and may at the very least, be considered to be a benign addition.

"A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.).

Applicants further argue that the insulin concentrations disclosed in '471 and '824 are for entirely different solutions. However, the solutions are both disclosed to be perfusion solutions for organs, particular kidney which is an organ. The solution presently claimed is for use of cold storage and perfusion of organs. Thus, all three solutions, the claimed solution and the two solutions of the prior art, are used for the same purpose.

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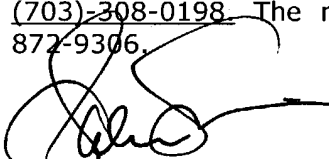
Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.



Sandra Saucier
Primary Examiner
Art Unit 1651
March 3, 2004